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On 13 September 2012 Merck Sharpe and Dohme Corp. (Merck) received 18 30-count bottles of Singulair® 10mg from the Federal Bureau of Investigation (FBI) New York Field Office. Merck was requested to analyze the specimens for evidence of counterfeiting and exposure to foreign solvents.

The specimens were received in two plastic bags, containing eight and ten bottles respectively (Figure 1). Representative images of the bottles received are shown in Figure 2. The bottles contained several different lot numbers and had expiry dates ranging from 2011 through 2013.

Merck initiated a suspected counterfeit investigation on the submitted specimens, tracked internally as Case 2012-09-00065. A forensic analysis was performed on a representative sampling of the specimens by Merck's Analytical Chemistry laboratory in West Point, Pennsylvania. The forensic testing included a physical analysis of the suspect packaging components and tablets and comparisons to authentic control samples. Chemical analyses of the suspect packaging and product were also completed.

The laboratory analysis concluded the packaging components were physically consistent with authentic Merck materials used to package Singulair® 10mg for distribution in the United States. The analysis further concluded the packaging components were contaminated by an exposure to a foreign organic solvent. This solvent was not found in the control sample components. Foreign solvents were found to be absorbed in the plastic bottle and desiccant cartridges inside the bottles.

The Singulair® 10mg tablets contained within the bottles were concluded to be consistent with authentic Merck tablets. However, the tablets were also found to be contaminated with a foreign organic solvent not found in the control tablets (Figure 3).

Detection and identification of the foreign organic solvent was completed by gas chromatography – mass spectroscopy (GC-MS). The foreign solvent was detected in the suspect bottles, desiccant cartridges, and tablets. Identification of the solvent determined that it was comprised of a mixture of long-chain hydrocarbons, consistent with those found in commonly accessible materials such as naphtha-based lighter fluid and mineral spirits. The foreign solvent was not detected in control materials analyzed under the same conditions.

[redacted]

Further action on this information will be left to the discretion of the local authorities. Merck requests it be notified prior to any public announcement relative to the information provided herein.

Sincerely,

Anthony Zook, PhD
Merck Global Security
Director Product Integrity
Merck Sharp & Dohme Corp.

[redacted]

FIGURES

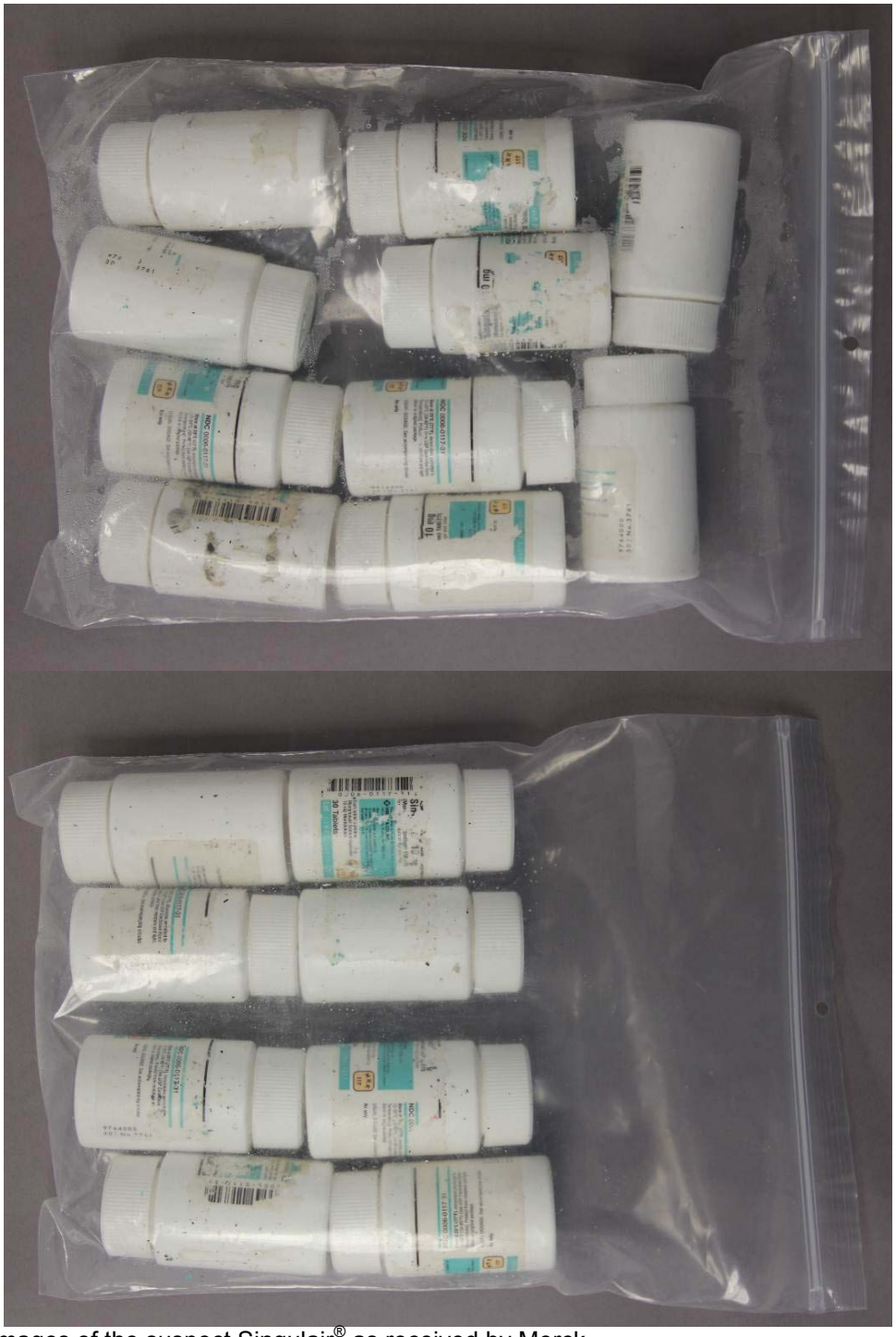

Figure 1 – Images of the suspect Singulair® as received by Merck

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[redacted]

Figure 2 – Representative images of the suspect Singulair® bottles

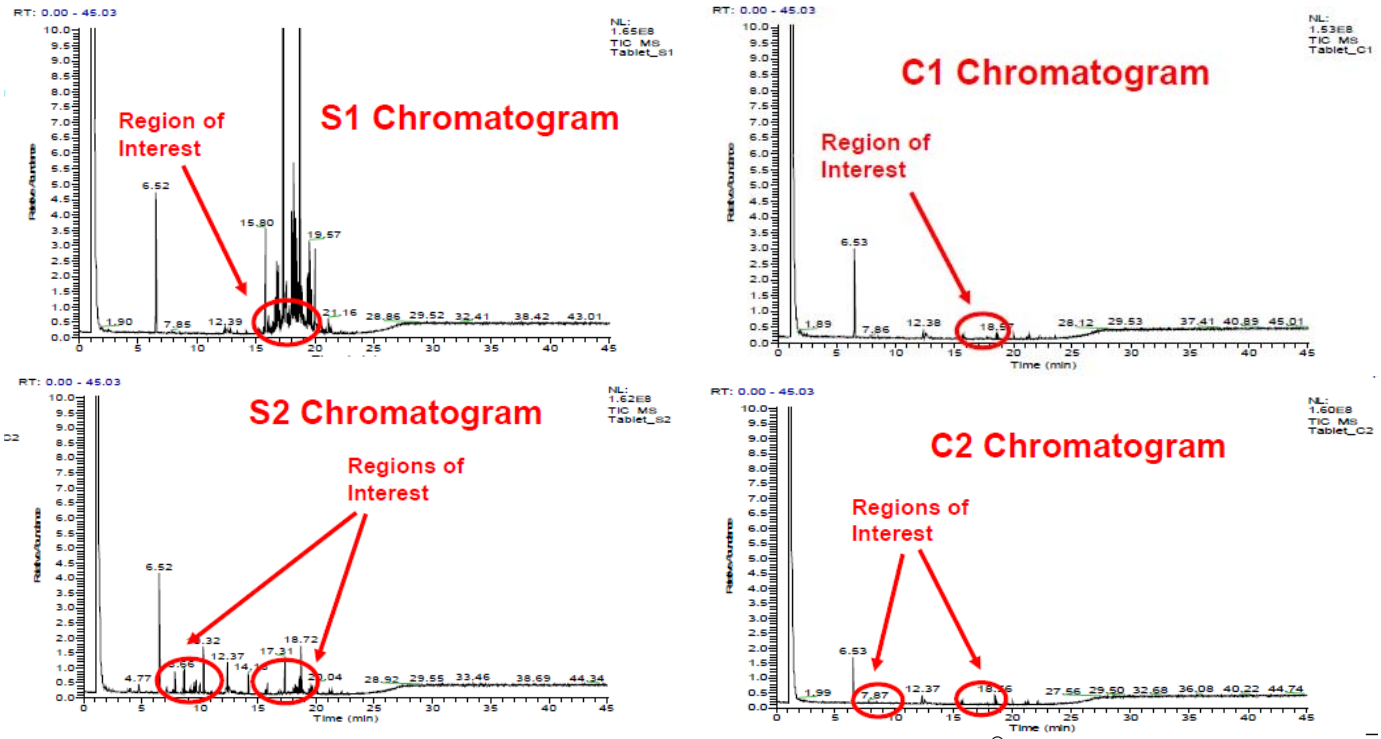

Figure 3 – Representative GC chromatograms of two sets of suspect Singulair® tablets; S1 and S2 denote samples submitted for testing and C1 and C2 are control samples